K091880

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510(k) SUMMARY

Clayton Intra-aural Device (CID)

FEB 2 4 2010

1. Submitter's Identification:

Ascentia Health, Inc.
5330 Parliament Place
Rockford, Illinois 61107
815.519.6939

Contact Person: Roger Wixtrom, Ph.D.
703.646.5820 (office)
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2. Date Summary Prepared:

February 16, 2010

3. Name of the Device:

Common Name: Intra-aural Appliance
Proprietary Name: Clayton Intra-aural Device (CID)

4. Predicate Device Information:

The CID is substantially equivalent to the following predicate devices:

1. Custom-fit flat plane occlusal appliances (also referred to as stabilization splints or mouthguards) "individually fabricated for each patient by dentists in their offices since at least the 1940s;" and
2. NTI-Clenching Suppression System (K981546), Heraeus Kulzer, Incorporated.

5. Device Description:

The CID is comprised of a pair of small, hollow, ear inserts made of medical grade polymers that is custom-fit to each subject's ear canals. It is constructed from methacrylate polymers and similar rigid plastics that have been safely used in commercially available hearing aids for decades. The CID is designed to rest in the outer third of the ear canal and has a small retraction post that allows for ease of removal of the device from the ear canal. It is designed to conform to the shape of the ear canal when the jaw is in a slightly open position.

The CID represents a non-invasive, reversible treatment modality. The ear canal is in immediate anatomical proximity to the temporomandibular joint (TMJ). The position of the condyle and disc within the TMJ, relative to the ear canal, differs depending on whether the jaw is in an opened or closed position,

and a change in the configuration of the ear canal also accompanies the opening or closing of the jaw.

6. Intended Use:

The CID is indicated as an aid in reducing temporomandibular disorder (TMD) pain.

7. Comparison to Predicate Devices:

Comparison of Characteristics Between CID and Predicate Devices

Characteristic	CID	Custom-fit Flat Plane Occlusal Appliances (Stabilization Splints)	NTI-Clenching Suppression System (K981546)
Indications for use	"The CID is indicated as an aid in reducing temporomandibular disorder (TMD) pain."	"Stabilization splints are the most widely used treatments for TMJ disorders" (NIDCR. 2006. *TMJ Disorders.* NIH Publication No. 06-3487).	"For the prevention of chronic tension and temporal mandibular joint syndrome that is caused by chronic clenching of the posterior mandibular and maxillary teeth by the temporalis muscle. The device is custom made for the individual."
Target population	Patients with or susceptible to TMD	Patients with or susceptible to TMD	Patients with or susceptible to TMD
Anatomical site	Targeted to relieve tension in temporomandibular joint (TMJ) – positioned in ear canal during patient use (*i.e.*, "near-field" to TMJ)	Targeted to relieve tension in temporomandibular joint (TMJ) – positioned in mouth during patient use (*i.e.*, "far-field" to TMJ)	Targeted to relieve tension in temporomandibular joint (TMJ) – positioned in mouth during patient use *i.e.*, "far-field" to TMJ)
Reversibility of treatment	Reversible, non-invasive treatment	Reversible, non-invasive treatment	Reversible, non-invasive treatment
Rx vs. OTC	Prescription-only	Prescription-only	Prescription-only
Where used	Worn daily by patient	Worn daily by patient	Worn daily by patient
Materials, biocompatibility and chemical safety	Methacrylate polymers and similar rigid plastics that have been safely used in commercially available hearing aids for decades.	Methacrylate polymers and similar rigid polymers, as well as soft polymers, that have a long history of safe use in stabilization splints.	Polycarbonate plastic with long history of safe use in tissue contact applications
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile

With respect to the target population, indications for use and anatomical site, all three are targeted at patients experiencing or susceptible to temporomandibular disorders (TMD) and aim to reduce the tension on the temporomandibular joint (TMJ), with the CID acting on the TMJ from a somewhat closer location (the ear canal), as compared to the stabilization splints and NTI- Clenching Suppression

System, which act from a more forward location between the teeth. All three provide the widely-recommended option of reversible, non-invasive treatments, are provided by prescription only and are typically worn on a daily basis by patients. The materials used to construct all three devices have a long history of safe use, without issues of chemical safety. Lastly, all three are provided non-sterile.

The strongest evidence supporting the substantial equivalence of the CID to the predicate devices is provided by the clinical testing of this device alongside the predicate device in a randomized clinical trial.

Based on the entire body of available information, including many similarities, as well as some differences, the latter of which have been demonstrated not to adversely affect safety and effectiveness, the comparison between the CID and the predicate devices demonstrates substantial equivalency.

8. **Performance Data:**

The safety and effectiveness of the CID, as well as the stabilization splint predicate comparison devices, in treating subjects with temporomandibular disorders was evaluated in a prospective, open-label, three-arm, randomized, unblinded clinical trial with a pre-treatment screening phase, baseline visit and three-month treatment phase. The study specifically addressed patients with TMD diagnoses (RDC/TMD criteria) included at least one of the following: myofascial pain; arthralgia, or disc displacement with reduction; and a screening VAS pain score of >4. The distribution of RDC/TMD diagnoses was very similar in all 3 treatment groups: I:Myofascial Pain (97-100%); II-a:Disc Displacement with Reduction (45-48%); and III-a: Arthralgia (55-61%). The study included 60 patients in the CID group, 64 patients in the stabilization splint group, and 28 patients in the jaw exercise regimen group. Patients in the CID group wore the device for an average of 18 hours per day in the first month, 20 hours per day in the second month and 21 hours per day in the third month.

The CID demonstrated statistically significant non-inferiority to the stabilization splint (p=0.0096), as assessed by reduction of Craniomandibular Index (CMI) scores from baseline to 3 months [primary efficacy objective]. The CMI scores were reduced in all treatment groups at 1, 2 and 3 months (with lower CMI scores representing reduced pain and dysfunction). Although the differences between study groups did not rise to the level of statistical significance, the average percentage changes in

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CMI scores from baseline to 1 month were: CID 27% reduction, stabilization splint 20% reduction, and jaw exercise regimen 12% reduction; and from baseline to 3 months, the percentage changes in CMI scores were: CID 45% reduction, stabilization splint 41% reduction, and jaw exercise regimen 36% reduction.

Statistically significant reductions from baseline in TMD pain, as assessed by in-office VAS (visual analog scale) scores, were also demonstrated for the CID device, with a 46% reduction at 1 month ($p<0.0001$), 51% reduction at 2 months ($p<0.0001$), and a 58% reduction at 3 months ($p<0.0001$). Statistically significant reductions of in-office VAS scores were also observed for the stabilization splint group (31% reduction at 1 month, 47% at 2 months, and 49% at 3 months) and jaw exercise regimen groups (18% reduction at 1 month, 37% at 2 months, and 51% at 3 months), with the differences between the three groups not statistically significant.

Patient global satisfaction in the study was very high with 100% of subjects in CID group indicating either excellent (71%) or good (29%) overall satisfaction with the device.

The primary safety objective of the study was to characterize the safety profile of the CID by collecting and reporting study-related adverse events. There were no unanticipated adverse device effects or serious adverse events reported during the study. No study patients were found to have ear drainage, allergic reactions, swelling or changes to the mouth, ear or jaw at any of the follow-up visits. There were no reports of diminished hearing acuity in patients treated with the CID.

Treatment-Related Adverse Events Observed in the CID Randomized Clinical Trial

	Treatment Group		
	CID (N = 60)	Stabilization Splint (N = 64)	Exercise Regimen (N = 28)
Non-Serious Treatment-Related Adverse Events			
Discomfort or Pain	6.7% (4/60)	9.4% (6/64)	7.1% (2/28)
Increased TMD Symptoms	1.7% (1/60)	0% (0/64)	0% (0/28)
Diminished Hearing Acuity	0% (0/60)	1.6% (1/64)	0% (0/28)
Headache	5.0% (3/60)	4.7% (3/64)	3.6% (1/28)
Dizziness or Nausea	1.7% (1/60)	3.1% (2/64)	3.6% (1/28)
Other	3.3% (2/60)	3.1% (2/64)	0% (0/28)

Numbers are Percent of Subjects with Event (# Subjects with Event/Total # Subjects).
"Other" events in the CID group include a single report each of "sensation in the ear" (starting on day 8, lasting 11 days) and "ringing in both ears" (starting and ending on day 4); and in the stabilization splint group a single report each of "musculature contracture" (starting on day 47, lasting 33 days) and "inflammation of gums" (starting on day 33, lasting 1 day).

The most frequently reported treatment-related adverse event in all three groups was discomfort or pain. The CID group, stabilization splint group and exercise group had an incidence of discomfort or pain of 6.7%, 9.4% and 7.1%, respectively. The second most frequently reported treatment-related adverse event was headache, which was reported in 5.0% of CID subjects, 4.7% of stabilization splint group subjects and 3.6% of exercise group subjects. The CID was shown to have a safety profile that was not statistically significantly different from the stabilization splint (p-value = 0.688).

The three-month randomized clinical trial demonstrated the CID to be as safe and effective, and to perform as well as the stabilization splint predicate devices (also commonly referred to as custom-fit flat plane occlusal appliances), in the treatment of TMD, with high levels of patient satisfaction and statistically significant reductions in TMD pain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 9 2010

Ascentia Health, Incorporated
C/O Roger Wixtrom, Ph.D.
5330 Parliament Place
Rockford, Illinois 61107

Re: K091880
Trade/Device Name: Clayton Intra-Aural Divice (CID)
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQC
Dated: February 16, 2010
Received: February 17, 2010

Dear Dr. Wixtrom:

This letter corrects our substantially equivalent letter of February 24, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

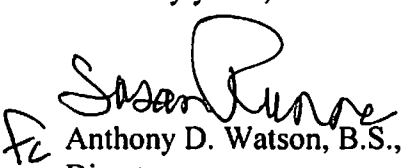
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use

510(k) Number (if known): K091880

Device Name: Clayton Intra-aural Device (CID)

Indications for Use:

The CID is indicated as an aid in reducing temporomandibular disorder (TMD) pain.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091880